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**APPLICATION NUMBER: 020924**

**PHARMACOLOGY REVIEW(S)**

NDA 20-924

Review Completed: October 27, 1998

Sponsor: Baxter Healthcare Corporation; Route 120 and Wilson Road; RLT-10; Round Lake, IL 60073

Date Submitted: March 20, 1998

Date Received: March 23, 1998

DRUG: Cernivit™-12 IV multivitamins (water and fat soluble mixed micelle formulation)

CATEGORY: vitamins

/S/

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10/27/98

cc: NDA Arch  
HFD510  
HFD510/Steigerwalt/McCort  
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**PHARMACOLOGY REVIEW OF NDA**  
**NDA 20-924 Initial NDA (March 20, 1998)**

**DRUG:** Cernivit™-12 IV multivitamins (fat and water-soluble vitamins in a mixed micelle formulation) (this does not include vitamin K).

**CATEGORY:** Parenteral vitamins

**INDICATION:** Daily IV administration for adults and children > 11 years old on parenteral nutrition. This is for nutritional supplementation, not treatment of vitamin deficiencies.

**DOSAGE:** One vial is reconstituted in 5 ml of sterile water for injection, USP and administered by intravenous infusion. For children >11 years old and adults, recommended dose is one vial (5 ml/day).

**PREVIOUS MARKETING EXPERIENCE:** Currently marketed in Europe since 1982. Due to vitamin shortage in the US, Cernivit™-12 has been imported for use in the United States since 1996.

**PHARMACOLOGY REVIEW OF ORIGINAL NDA SUBMISSION**  
**(Original submission dated March 20, 1998)**

**BACKGROUND:** Cernivit™-12 IV Multivitamins has been marketed in Europe since 1982. Due to vitamin shortage in the US, Cernivit™-12 IV Multivitamins has been imported for use in the United States since 1996. The sponsor is relying on the FDA finding of safety of Astra's M.V.I® - 12 product, NDA 8-809/S004 (approved August 1985) no right of reference is cited. The cited product is of similar composition to the Baxter product with minor changes in the levels of some vitamin components, which would not appear to be toxicologically important. The sponsor has provided some preclinical studies to support the use of the mixed micelle formulation of this product. A copy of the Handbook of vitamins was supplied in support of vitamin levels used in this formulation.